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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,187	06/12/2002	Michael Hallek	50125/045001	2548
21559 7590 01/09/2007 CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER HURT, SHARON L	
			ART UNIT	PAPER NUMBER
			1648	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/031,187	Applicant(s) HALLEK ET AL.	
	Examiner Sharon Hurt	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-29,33,36-43,45,47,49,51,53,55,57,59 and 65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29,33,36-43,45,47,49,51,53,55,57,59 and 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>July 17, 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Specification

The amendments to the specification and claims, filed September 21, 2006, have been acknowledged.

Status of the Claims

Claims 27, 29, 36-37, 42-43 and 55 are currently amended. Claims 1-26, 30-32, 34-35, 44, 46, 48, 50, 52, 54, 56, 58 and 60-64 are cancelled. Claims 27-29, 33, 36-43, 45, 47, 49, 51, 53, 55, 57, 59 and 65 are pending and under examination on the merits.

Response to Arguments

Rejections Withdrawn

The rejection of claims 27-29, 33-34, 36-43, 45, 47, 49, 51, 53, 55, 57, 59 and 65 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** pursuant applicant's amendments. The rejection is directed to the broad claim, which reads on any mutation before or after at least one amino acid sequence. Applicant's arguments filed September 21, 2006 have been fully considered and are persuasive.

The rejection of claims 27-29, 33-34, 36-43, 45, 47, 49, 51, 53, 55, 57, 59 and 65 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is

withdrawn pursuant applicant's amendments. Applicant's arguments have been fully considered and are persuasive.

Rejections Maintained

The rejection of claims 27-29, 36, 38-43, 45 and 47 under 35 U.S.C. 102(e) as being anticipated by Rabinowitz et al. (US Patent No; 6,491,907) **is maintained**. The claimed invention is of record. The teachings of Rabinowitz et al. (hereinafter Rabinowitz) are of record. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that the amendment to claim 27 has overcome the rejection because the insertion, previously anywhere in the recited sequences, is now positioned in or directly adjacent to the AAV capsid location. Rabinowitz teaches that more than one exogenous targeting sequence may be introduced in to the parvovirus capsid including insertions within the minor capsid subunits VP3 of AAV (Column 21, lines 20-29).

The rejection of claim 37 under 35 U.S.C. 103(a) as being unpatentable over Rabinowitz et al. in view of Skubitz et al. (US Patent No: 5,276,136) **is maintained**. The claimed invention is of record. The teachings of Rabinowitz are of record. The teachings of Skubitz et al. (hereinafter Skubitz) are of record. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that Skubitz fails to disclose anything about AAV therefore they cannot suggest the claimed AAV purification technique. Rabinowitz teaches about AAV and Skubitz teaches the claimed sequence. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually

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where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The rejection of claims 47, 49, 51, 53, 55, 57 and 59 under 35 U.S.C. 103(a) as being unpatentable over Rabinowitz et al. in view of Spear et al. or Yang et al. **is maintained** for reasons of record. The claimed invention is of record. The teachings of Rabinowitz, Spear and Yang are of record. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that the rejection is based on the assertion that the mutations are located anywhere in the AAV capsid sequence. Applicant believes that the amendments to the claims overcome the rejection. The teachings of Rabinowitz as cited above show that the insertions can be made within the VP3 of AAV; therefore, the rejection stands.

The rejection of claim 59 under 35 U.S.C. 103(a) as being unpatentable over Rabinowitz et al. in view of Ruffing et al. **is maintained** for reasons of record. The claimed invention is of record. The teachings of Rabinowitz and Ruffing are of record. Applicant did not submit an argument pointing out disagreements with the examiner's contentions.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 27 and 29 have been amended and now introduce new matter which is not adequately described in the specification. Claims 27 now recites that the insertion is located “directly adjacent to an amino acid” and that said “insertion” bring about an alteration in the chromatographic properties of the virus. The specification does not disclose an insertion directly adjacent to an amino acid. The specification does not disclose that insertion brings about an alteration in the chromatographic properties of the virus. The specification does disclose that a mutation brings about an alteration in the chromatographic properties of the virus (page 4, lines 24-27). This matter might be resolved if applicant were to point to exactly wher in the specification support for the newly recited material may be found.

If the new matter is removed from the claims the withdrawn rejections under 35 U.S.C. 112, second paragraph and first paragraph, will be reinstated.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

28 December 2006


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